

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date	5.17.99
Publication Date	5.20
Certifier	C. WMS DIX

Food and Drug Administration

Transmissible Spongiform Encephalopathies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Transmissible Spongiform Encephalopathies Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 2, 1999, 8:30 a.m. to 5:30 p.m., and June 3, 1999, 8:30 a.m. to 4 p.m.

Location: Holiday Inn, Ballroom II, Montgomery Village Ave., Gaithersburg, MD.

Contact Person: William Freas or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12392. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 2, 1999, the committee will continue the discussion from its December 18, 1998, meeting on the possible deferral of blood or blood product donors based on geographical criteria linked to possible food-borne exposure to the agent of bovine spongiform encephalopathy as a measure to reduce the potential for transmission of new variant Creutzfeldt-Jakob Disease (nvCJD). The transcripts of the December meeting are available on the FDA home page (<http://www.fda.gov/ohrms/dockets/ac/98tctm.htm>). The potential effects of such deferrals on the supply

of blood and blood products will be considered as part of the committee's deliberations. The results of a survey of blood donors for duration and time periods of their visits to U.K. countries are expected to be presented. On June 3, 1999, the committee will receive an update on dura mater allograft materials. The committee will then discuss precautions needed to assure safe sources of sheep-derived and goat-derived materials contained in or used to manufacture injectable or implantable FDA-regulated products.

Procedure: On June 2, 1999, from 8:30 a.m. to 5:30 p.m., and June 3, 1999, from 8:30 a.m. to 3:45 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 26, 1999. Oral presentations from the public will be scheduled between approximately 1:45 p.m. and 2:45 p.m. on June 2, 1999, and between 1 p.m. and 1:30 p.m. on June 3, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 26, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On June 3, 1999, from 3:45 p.m. to 4 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of this material.

FDA regrets that it was unable to publish this notice 15 days prior to the June 2, 1999, Transmissible Spongiform Encephalopathies Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Transmissible Spongiform Encephalopathies Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: May 11, 1999



Michael A. Friedman
Deputy Commissioner for
Operations

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

